

REMARKS

Claims 1 – 8, 10 – 22, 24 – 28 and 30 -32 are pending in this application with claims 1 – 3 and 20 being withdrawn from consideration. Claims 4, 5, 10, 13, 18, 21, 30, 32 and 33 being amended by this response. Specifically claims 4, 5, 10, 13, 18, 21, 30, 32 and 33 are formally amended for purposes of clarity to state that “upon application by a user said composition is able to relieve any of the itch, pain and swelling caused by the insect bites and stings at said site is able to at said site”. Support for these amendments is found on page 4 of the present specification wherein a composition is described having “an abrasive for treating effects such as itching, pain and swelling resulting from insect bites and stings” that includes the “relief of allergenic reactions caused by insect bites and stings” and “alleviate[s] the discomfort associated with an insect bite or sting **by way of an abrasive action**”. Further on page 4, it is provided that the composition is “able to reduce any itching associated with the insect bite or sting”. This remedial effect which “is able to relieve any of the itch, pain and swelling caused by the insect bites and stings at said site is able to at said site” occurs when “the instant cream is rubbed on the bite or sting affected area, it appears that the active abrasive ingredients draw the allergenic or poisonous substance from the affected area along with any body materials resulting from swelling or infection” (see application, page 7, para.2).

Furthermore, submitted herewith is a Declaration of the inventor, Patrick Kennedy, who has personally developed, tested and successfully used the present claimed composition. As declared, Patrick Kennedy has successfully tested the claimed composition on both himself and other persons. The attached Declaration attests to the successful accomplishment of the claimed goal which is “to relieve any of the itch, pain and swelling caused by the insect bites and stings at said site is able to at said site”.

Additionally, claims 4, 5, 10, 13, 18, 21, 30, 32 and 33 were amended to delete any form of “glass” from the markush group contained in each claim.

Thus, in view of the above remarks, it is respectfully submitted that no new matter is added by this response.

Rejection of Claims 4-8, 10 – 19, 21 – 22, 24 – 28 and 30 - 32 under 35 U.S.C. 112, first paragraph

Claims 4-8, 10 – 19, 21 - 22, 24 – 28 and 30 – 33 stand rejected under 35 U.S.C. 112, first paragraph as not meeting the enablement requirement. Applicant assumes that the Examiner intended to reject claim 33 on the same grounds and thus the arguments regarding claim 33 are included in this response.

In view of the amendments to claims 4, 5, 10, 13, 18, 21, 30, 32 and 33 which delete the rejected claim language, Applicant has further amended these claims to recite “upon application by a user said composition is able to relieve any of the itch, pain and swelling caused by the insect bites and stings at said site is able to at said site”. In view of the support for the claim amendments in the present specification and discussed above, Applicant respectfully submits that this rejection is moot and that the present invention as claimed in claims 4, 5, 10, 13, 18, 21, 30, 32 and 33 is fully enabled under 35 USC 112, first paragraph.

In view of the above remarks, it is respectfully submitted that the present specification fully enables claims 4 – 8, 10 – 19, 21 – 22, 24 – 28 and 30 – 32 as required under 35 USC 112, first paragraph. Thus, it is further respectfully submitted that this rejection has been satisfied and should be withdrawn.

Rejection of Claims 4, 6, 10, 11, 21, 22, 24, 25, 26, 30, and 31 under 35 USC 102(b)

Claims 4, 6, 10, 11, 21, 22, 24, 25, 26, 30, and 31 stand rejected under 35 USC 102(b) as being anticipated by Lee (WO 99/37287) for reasons stated in the Office Action

The present invention recites a pharmaceutical composition for topical application to a site of insect bites and stings to relieve any of itch, pain, and swelling associated therewith. The composition consists of an effective amount of an abrasive ingredient and a carrier. Upon application by a user, the composition is able to relieve any of the itch, pain and swelling caused by the insect bites and stings at the site. The abrasive ingredient is selected from the group consisting of walnut shell, pumice, plastic material, sand, stone, seed shell, fruit shell, seed, metal, chitosan and ground crab shell and the carrier is selected from the group consisting of vegetable oil, fruit oil, soap, surfactant, lubricant, mineral oil, petrolatum, gel, lotion, emollient, white petroleum, beeswax, di-propylene glycol, gum, lubricating jelly and olive oil. Independent claims 10, 21 and 30 include similar limitations as discussed above.

Lee discloses a method for treating inflammatory symptoms such as burning, redness, itching and swelling and pain which accompany skin disorders other than wounds of the skin. The method includes topical application of a medicinal composition comprising a non-interlinked particulate bioactive glass mixed with a topical medicinal carrier to the site of the skin disorder. Lee clearly relies on a specific property of the glass, bioactivity, in order for the invention as disclosed therein to function properly. Lee defines bioactive glass as “glass material having an oxide of silicon as a major component and capable of bonding with growing tissue when reacted with physiological fluids” (see Lee, page 2, lines 17 – 19). The bioactive glass of Lee is a healing agent which biologically bonds with growing tissue and is thus wholly unlike the “abrasive ingredient” of the

present claimed invention.

Furthermore, in view of the above amendments to the claims, the present claimed invention does not include “glass” in any form as the “abrasive ingredient” of the present claimed invention.

As Lee discloses a composition for healing tissue using glass, Applicant respectfully submits that Lee neither discloses nor suggests a “pharmaceutical composition...consisting of an effective amount of an abrasive ingredient and a carrier, wherein upon application by a user said composition is able to relieve any of the itch, pain and swelling caused by the insect bites and stings at said site” as in the present claimed invention.

It is respectfully submitted that in view of the above remarks and amendments to claims, that there is no 35 USC 112 enabling disclosure present in Lee that anticipates the present invention as claimed in claims 4, 10, 21 and 30. As claim 6 is dependent on claim 4, claim 11 is dependent on claim 10, claims 22 – 26 are dependent on claim 21 and claim 31 is dependent on claim 30, it is respectfully submitted that claims 6, 11, 22 – 26 and 31 are patentable for the same reasons discussed above regarding claims 4, 10, 21 and 30. Thus, it is respectfully submitted that this rejection has been satisfied and should be withdrawn.

Rejection of Claims 7, 8, 27 and 28 under 35 USC 103(a)

Claims 7, 8, 27 and 28 stand rejected under 35 USC 103(a) as being unpatentable over Lee (WO 99/37287) as applied to claims 4, 6, 10, 11, 21, 22, 25, 26, 30 and 31 for the reasons stated in the Office Action.

As discussed above, Lee discloses a method for treating inflammatory symptoms such as burning, redness, itching and swelling and pain which accompany skin disorders other than wounds of the skin. The mixture disclosed by Lee includes bioactive glass which is of paramount importance in accomplishing the goal set forth by Lee. Specifically, the bioactivity of the glass is a property that must be maintained in order for the Lee mixture to be effective. Additionally, Lee specifically sets forth a preferred time period in which the mixture may be formed in order for the mixture to accomplish the desired affect of treating the skin disorder. To that effect, Lee states “if the two ingredients are mixed several days prior to application, e.g. one week, the ability of the composition to mitigate the inflammation may be compromised. This problem is particularly acute if the carrier causes bioactive glass to pre-react in a way that reduces the bioactivity of the glass.” (see Lee, page 5, lines 8 – 12). Thus, Lee clearly and unequivocally relies on a specific property of the glass, bioactivity, in order for the invention as disclosed therein to function properly. Lee defines bioactive glass as “glass material having an oxide of silicon as a major component and capable of bonding with growing tissue when reacted with physiological fluids” (see Lee, page 2, lines 17 – 19).

The present claimed invention performs a unique and wholly unrelated function than the one performed by the Lee mixture. The bioactive glass of Lee is not analogous and cannot be equivalent to or substituted with the “abrasive ingredient” as in the present claimed invention. Firstly, the present claimed invention does not include “glass” in any form as a listed abrasive ingredient. Secondly, in order for the mixture of Lee to function properly, a biochemical reaction must take place between the bioactive glass in the mixture and the tissue and fluids of the skin. The present claimed invention does not function in this manner achieves its objective goal based solely on the application of the composition. The reaction required by Lee is neither necessary nor claimed. Specifically, it is the mechanical application by a user of the composition that “is able to relieve any of the itch,

pain and swelling caused by the insect bites and stings at said site” as in the present claimed invention. As no biochemical reaction is required, Applicant respectfully submits that it would not be obvious to modify Lee to produce the present claimed invention because Lee would directly cease to operate in its desired manner. Furthermore, any reading of Lee that results in the bioactive glass being viewed as an abrasive is in direct conflict with teaching set forth therein and described hereinabove and in prior responses.

It is respectfully submitted that in view of the above remarks and amendments to the claims that there is no 35 USC 112 enabling disclosure present in Lee that makes the present invention as claimed in claims 4, 10, 21 and 30 unpatentable. As claims 7 and 8 are dependent on claim 4 and claims 27 – 28 are dependent on claim 21, it is respectfully submitted that claims 7, 8, 27 and 28 are patentable for the same reasons discussed above regarding claims 4 and 21. Thus, it is respectfully submitted that this rejection has been satisfied and should be withdrawn.

Rejection of Claims 5, 12 – 19 and 32 under 35 USC 103(a)

Claims 5, 12 – 19, and 32 stand rejected under 35 USC 103(a) as being unpatentable over Lee (WO 99/37287) as applied to claims 4, 6, 10, 11, 21, 22, 25, 26, 30 and 31, and further in view of Rubin (U.S. 5,543,149) for the reasons stated in the Office Action.

As discussed above, Lee neither discloses nor suggests a “pharmaceutical composition...consisting of an effective amount of an abrasive ingredient and a carrier, wherein upon application by a user said composition is able to relieve any of the itch, pain and swelling caused by the insect bites and stings at said site” as in the present claimed invention. In fact, the composition disclosed by Lee is more akin to a healing

agent as the bioactive glass includes certain properties that allow tissue to bond therewith and thus is not an abrasive ingredient as claimed in the present invention.

Rubin discloses a method of treating insect bites with digestive enzymes such as papain and pancreatin. However, similarly to Lee, Rubin neither discloses nor suggests a composition including “an effective amount of abrasive ingredient and a carrier, wherein upon application by a user said composition is able to relieve any of the itch, pain and swelling caused by the insect bites and stings at said site” as in the present claimed invention.

Additionally, Applicant respectfully submits that even if the composition of Lee was combined with the composition of Rubin, the resulting composition would not be a “pharmaceutical carrier...consisting of an effective amount of an abrasive ingredient and a carrier, wherein upon application by a user said composition is able to relieve any of the itch, pain and swelling caused by the insect bites and stings at said site” as in the present claimed invention. Rather, the resulting composition would be a lotion having bioactive glass and papain that, upon application increases the healing of the wound due to the properties of the bioactive glass while simultaneously reducing the itch and discomfort of the wound. The effects of the insect bite treated with a composition of Lee and Rubin would require the active work or enzymes or another biochemical reaction in order to perform the intended effect. This resulting composition would not be able to function like the present claimed invention which does not need any additional reactivity beyond application in order to “relieve any of the itch, pain and swelling caused by the insect bites and stings at said site”. As the combination of Lee with Rubin produces a fundamentally different composition than the composition of the present claimed invention, it would not be obvious to combine Lee with Rubin to produce the present claimed invention.

In view of the above remarks and amendments to the claims Rubin when taken alone or in combination with Lee provides no 35 USC 112 enabling disclosure that makes the present invention as claimed in claims 5, 13, 18 and 32 unpatentable. As claim 12 is dependent on claim 5, claims 14 – 17 are dependent on claim 13 and claim 19 is dependent on claim 18, it is respectfully submitted that claims 5, 14 – 17 and 19 are patentable for the same reasons as discussed above regarding claims 5, 13 and 18 respectively. Thus, it is further respectfully submitted that this rejection has been satisfied and should be withdrawn.

Having fully addressed the Examiner's rejections, it is believed that, in view of the preceding amendments, this application stands in condition for allowance. Accordingly then, reconsideration and allowance are respectfully solicited. If, however, the Examiner is of the opinion that such action cannot be taken, the Examiner is invited to contact the applicant's attorney at the phone number below, so that a mutually convenient date and time for a telephonic interview may be scheduled.

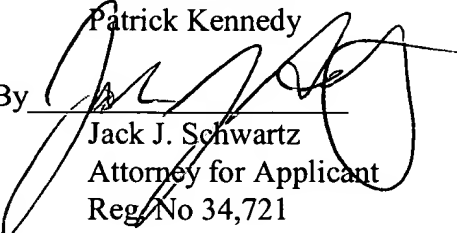
No additional fee is believed due with this response. However, should a fee be due please charge the fee to Deposit Account No. 50-2828.

In light of the foregoing, the application is now believed to be in proper form for allowance of all claims and notice to that effect is earnestly solicited.

Respectfully submitted,

Patrick Kennedy

By



Jack J. Schwartz

Attorney for Applicant

Reg. No 34,721

Jack Schwartz & Associates
1350 Broadway, Suite 1510
New York, New York 10018
Tel. No. (212) 971-0416
Date: September 2, 2005

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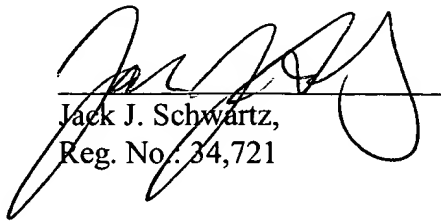
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I hereby certify that this amendment is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to the Mail Stop RCE, Commissioners for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

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Date



Jack J. Schwartz,
Reg. No. 34,721